REMARKS

Applicant acknowledges the obligation under 37 CFR 1.56 to point out the inventor and the invention dates of each claim that was not commonly owned at the time a later invention was made. The Examiner is correct in presuming that the subject matter of the claims in the present application was commonly owned at the time any inventions covered therein were made.

Claims 1-2, and 5-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Chen et al.* (U.S. Patent No. 6,383,471) in view of *Chopdekar et al.* (U.S. Patent No. 5,663,415).

The Examiner indicates that *Chen et al.* discloses the general teachings of converting one of the active pharmaceutical ingredients such as gabapentin (see col. 6, line 33) into its tannate salt complex (see col. 11, line 50) by protonating the basic groups of the gabapentin therapeutic agent. The Examiner further indicates that the ionizing agent is present in an amount of at least 0.1 mole equivalents per mole of ionizable functional groups (see col. 11, lines 56-59). The Examiner, however, acknowledges that the present invention differs from the prior art reference in that the claimed reaction temperature of 15-150°C is not disclosed and that the claimed pH is between 2 to 11.

Applicant asserts that the *Chen at al.* reference is not relevant prior art to the present application. *Chen et al.* relates only to "ionizable hydrophobic therapeutic agents" defined in the specification at col. 4, lines 53-59, as being compounds with little

or no water solubility at neutral pH. Intrinsic water solubilities "(i.e., water solubility of the unionized form) for the ionizable hydrophobic therapeutic agents usable in *Chen et al.* are less than about 1% by weight, and typically less than about 0.1% or 0.01% by weight." Furthermore, claim 1 and every independent claim in the *Chen et al.* patent requires that the pharmaceutical composition contain a hydrophobic therapeutic agent with an intrinsic water solubility of less than about 1% by weight. Gabapentin is not hydrophobic and does not have an intrinsic water solubility of less than about 1% by weight at neutral pH. In fact, gabapentin is hydrophilic. The Merck Index, Thirteenth Edition, states that gabapentin has a solubility in water at pH 7.4 which exceeds 10%. *Chen et al.* teach away from using a hydrophilic therapeutic agent such as gabapentin and thus cannot serve to create a prima facie case of obviousness. Clearly, gabapentin was erroneously included in the laundry list of approximately 500 "hydrophobic therapeutic agents" in the *Chen et al.* patent. A copy of the relevant portions of the Merck Index, Thirteenth Edition, is attached as Exhibit 1.

With regard to *Chopdekar et al.*, as the Examiner indicates, the reference discloses a process of preparing antihistamine tannates. The Examiner is correct in stating that *Chopdekar et al.* disclose a process for preparing pure **antihistamine** tannate compositions. The antihistamines disclosed in *Chopdekar et al.* include phenylephrine, carbetapentane, pyrilamine, chlorpheniramine, ephedrine, pseudoephedrine, brompheniramine, bromodiphenhydramine, diphenhydramine, pheniramine, phenyltoxamine, clemastine, tripelennamine, cyproheptadine, phenindamine and

phenyltoloxamine. Gabapentin, on the other hand, is characterized as an **anticonvulsant** and as a medication to relieve pain, especially neuropathic pain. Gabapentin is also considered a neuroleptic agent indicated as adjunctive therapy in the treatment of partial seizures, with and without secondary generalization, in adults with epilepsy, faintness attacks, hypokinesis and pain associated with shingles and cranial traumas. Clearly, **gabapentin is not an antihistamine**. Thus, *Chopdekar et al.* neither disclose nor suggest that gabapentin could be effectively incorporated into a tannate salt complex. And, as discussed above, the *Chen et al.* reference is limited to hydrophobic therapeutic agents which excludes gabapentin and cannot be combined with *Chopdekar et al.* to render pending claims 1-2 and 5-21 as being unpatentable under 35 U.S.C. 103(a).

Furthermore, Applicant indicates in the Specification of the present application that the formation of a tannate salt of gabapentin is unexpected because of the close proximity of a carboxylic acid group to the amine group. The negative charge on the carboxylic acid group was expected to shield and possibly neutralize the positive charge on the proximal nitrogen. Since tannate salts are thought to normally form through an ionic interaction with a positively charged amine functional group, the close proximity of the carboxylic acid group was expected to prevent the formation of the tannate salt.

In conclusion, Applicant asserts that all the pending claims meet the formal and substantive requirements of the patent laws and are in condition for allowance.

Accordingly, Applicant respectfully requests early issuance of the formal Notice of Allowance.

Respectfully submitted,

KING & SCHICKLI, PLLC

By: Warren D Schickli
Warren D. Schickli
Registration No. 31, 057

247 North Broadway
Lexington, Kentucky 40507
Phone: (859) 252-0889

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on 10 Aug 2006.

Edward Day Date: 8/10/06